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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,166	08/31/2001	David R. Elmaleh	MGA-003.01	1584
25181	7590	03/24/2004	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			ZARA, JANE J	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/945,166

Applicant(s)

ELMALEH ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 25-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the communication filed 11-17-03.

Claims 1-14 and 25-34 are pending in the instant application.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claims 1-3, 5-10, 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Rothschild et al for the reasons of record set forth in the Office action mailed 8-12-03.

Applicant's arguments filed 11-17-03 have been fully considered but they are not persuasive. Applicants argue that Rothschild does not teach every element of the claimed invention because the instant invention comprises three components, a targeting moiety localizing to a target site in an organism, an oligonucleotide complementary to a nucleic acid of interest and a detectable label. Contrary to Applicants' assertions, Rothschild discloses targeted oligonucleotide constructs comprising a targeting moiety (among such moieties include adhesion molecules targeting e.g. cell adhesion molecules including cell adhesion molecules LEC-CAM, ICAM-1, VCAM-1, ELAM-1, as well as lipid and nucleic acid binding proteins, see col. 7); comprising an oligonucleotide complementary to a nucleic acid of interest (e.g. see

col. 23, lines 50-53: "Resulting nucleic acid-conjugates can be used in PCR technologies, antisense therapy and prophylactic and diagnostic applications."); and comprising a detectable label (e.g. see col. 9, lines 45-49: "Detectable moieties should have a selectively detectable physical property such as fluorescence, absorption or an ability to specifically bind to a coupling agent such as avidin...").

Applicants argue that Rothschild teaches photocleavable group and therefore does not qualify as prior art since the instant invention does not claim a photocleavable group. Contrary to Applicants' assertions, the inclusion of a photocleavable group within the oligonucleotide construct does not disqualify Rothschild as prior art. The inclusion of a photocleavable group does not replace the three component oligonucleotide construct with a two component oligonucleotide construct, but instead adds another technical feature onto the invention. The oligonucleotide construct disclosed by Rothschild comprises a targeting moiety, an oligonucleotide complementary to a gene of interest, a detectable label and a photocleavable group. Rothschild therefore properly anticipates the claimed invention.

Claims 1-3, 5, 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Papahadjopoulos et al for the reasons of record set forth in the Office action mailed 8-12-03.

Applicant's arguments filed 11-17-03 have been fully considered but they are not persuasive. Applicants argue that Papahadjopoulos does not properly anticipate the claimed invention because the instant invention contemplates targeting moieties that

are molecular structures that assist the construct in localizing to a particular target area, and the nucleic acids of the instant invention are not the targeting moiety of the complex, as in the invention disclosed by Papahadjopoulos. Contrary to Applicants' assertions, Papahadjopoulos teaches targeting moieties that are non-nucleic acids (e.g. col. 13, lines 4-56, "The Fab' fragment is specifically bind to a molecule or marker characteristic of the surface of the cells to which it is desired to deliver the contents of the cationic lipid: nucleic acid complex." In addition, Papahadjopoulos teaches nucleic acids as effectors and includes antisense, ribozymes and labeled nucleic acids, which "can be targeted to desired cellular targets with a targeting moiety." (e.g. see col. 20, lines 52-67). Therefore, contrary to Applicants' assertions, Papahadjopoulos properly anticipates the claimed invention.

Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7, 12-14, 27 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 5-7, 12-14, lines 3-4, the metes and bounds of the phrase "any configuration that maintains the desired activity of said label and said moiety" cannot be determined (e.g. perhaps it would be remedial to replace this phrase with a delineation

as appropriate in each of the claims as to whether the targeting moiety, label, oligonucleotide are **each** coupled directly to each other, since this amendment was made to address the 112 second paragraph of 8-12-03; an example might include, e.g. for claim 5: in line 2, inserting –each—before “coupled”). Appropriate clarification is requested.

In claims 27 and 32, line 3, it is unclear what is meant by “phopshorothioate” (replacing this with –phosphorothioate—would be remedial).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 and 25-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Baird et al.

Baird et al teach targeted oligonucleotide constructs comprising a targeting moiety that localizes to a site in an organism, an antisense that specifically targets mRNA encoding c-myc and further comprises a phosphorothioate to enhance oligonucleotide stability or optionally comprises a biotin moiety, which construct additionally comprises a therapeutic agent, and which construct optionally further comprises a cell uptake facilitating moiety and a detectable (e.g. fluorescent) label (See especially the abstract; col. 5-8; col. 14-15; co. 18; col. 24-25).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Art Unit: 1635

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

JZ

3-18-04